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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,718	07/14/2000	Bert L. Vallee	11187-00001	5959
27716	7590	09/15/2006	EXAMINER	
CV THERAPEUTICS, INC. 3172 PORTER DRIVE PALO ALTO, CA 94304			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/616,718	Applicant(s) VALLEE ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicants' Amendment filed October 13, 2005 is acknowledged. Claims 1-3 and 13 are pending. Previous indications of both allowable subject matter and finality are withdrawn.

In response to the objection to the disclosure set forth in the last Office Action, claim 13 has been amended to recite the two aldehyde compounds 5-hydroxy-3-indole-3-acetaldehyde or 3,4-dihydroxyphenyl-acetaldehyde, and the term "neurotransmitter" has been replaced with "serotonin or dopamine". The objection is withdrawn.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2 and 13, drawn to methods for inhibiting ALDH-2 in a human and for reducing alcohol consumption both comprising administering a compound of instant Formula I.

II. Claim 3, drawn to methods for increasing the concentration of 5-hydroxy-3-indole-3-acetaldehyde or 3,4-dihydroxyphenyl-acetaldehyde formed during catabolism of serotonin or dopamine comprising administering a compound of instant Formula I.

The inventions are distinct, each from the other, for the following reasons:

The inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions have different effects. The enzyme ALDH-2 may be inhibited by administration of other compounds; alcohol consumption may be reduced through the administration of other compounds such as disulfiram. These are clearly different

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effects from increasing the concentration of 5-hydroxy-3-indole-3-acetaldehyde or 3,4-dihydroxyphenyl-acetaldehyde formed during catabolism of serotonin or dopamine.

The Groups have acquired a separate status in the art as shown by their recognized, divergent subject matter. The searches required for each Group are not co-extensive resulting in an undue burden to the Examiner. Each Group is capable of supporting a separate patent. Thus restriction for examination purposes as indicated is proper.

During a telephone conversation with J. Elin Hartrum on September 11, 2006, a provisional election was made to prosecute the invention of Group II, methods for increasing the concentration of 5-hydroxy-3-indole-3-acetaldehyde or 3,4-dihydroxyphenyl-acetaldehyde formed during catabolism of serotonin or dopamine, claim 3. Accordingly, claims 1, 2 and 13 are presently withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claim 3 is under consideration. Re-affirmation of the election is requested when Applicants respond to this Office Action.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because it is not drawn to the subject matter that is presently claimed. Correction is required. See MPEP § 608.01(b).

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Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In claim 3 the R group is substituted or unsubstituted. Those substituents that apply to any or all of the options for R, i.e., a sugar moiety, a peptide, a polyether or an aminoalkyl group, cannot be precisely determined. It is unclear what substituents are contemplated and to which option they are applicable. Applicants should recite those substituents contemplated for each of the options for the R term.

Claim 3 is denied.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 12, 2006


Phyllis G. Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**